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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,797	VISVADER ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *2,4,6,10-17,21,24-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,7-9,18-20,22,23 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

The Amendment filed on 8/4/06 in response to the previous Non-Final Office Action (1/3/06) is acknowledged and has been entered.

Claims 2, 4, 6, 10-17, 21, and 24-39 have been previously withdrawn for non-elected invention. Claim 18-20, 22, 23 have been amended. Claim 40 has been added. Claims 1-40 are pending. Claims 1, 3, 5, 7-9, 18-20, 22, 23 and 40 are under consideration.

The text of those sections of Title 35, U.S.Code not included in this action can be found in the prior Office Action.

The following office action contains NEW GROUNDS of rejection.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 2/4/05 are/is considered by the examiner and initialed copies/copy of the PTO-1449 are/is enclosed.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority also based on an application filed in Australia on 09/12/2001. Acknowledgment is also made of applicant's submission of a certified copy of the PR7618/01 to the Office on 8/25/06. However, upon review of specification of PR7618/01 applications, it is noted that the application does not provide a support for a method of detecting an aberrant cell comprising forming an immunointeractive molecule-LMO4 complex, wherein the immunointeractive molecule is an antibody to LMO4 secreted by hybridoma 16H2 or 20F8. Therefore, the claims comprising claim 20, 23, and any other claims encompassing using antibody 16H2 or 20F8 do not benefit the priority date of the application PR7618/01, 09/12/2001. If applicant disagree with any rejection set forth in this office action base on this priority date, applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

2. The Office has required applicants to submit a copy of parent Application, PCT/AU02/01246, since this application claims that it is a continuation of the Application, PCT/AU02/01246. Applicants

argue on page 12 of the response, "*applicants submit that the present application entered national stage for an international application after compliance with 35 USC 371*". In response to this argument, first, the instant application is not a national stage of international application, 35 USC 371, it is a continuation international application, PCT. Secondly, according to MPEP 1895.01, for a continuation of PCT application, a certified copy of the international application (PCT/AU02/01246) may be required by the examiner to perfect the claims for benefit under 35 USC120 and 365(c). The copy of receipt for PR7618/01 (exhibit A) from international bureau and certified copy of foreign application PR7618/01 could not replace the certified copy of Application, PCT/AU02/01246. Therefore, applicants are required to submit a certified copy of Application, PCT/AU02/01246, in order to obtain the benefit of the parent application, PCT/AU02/01246, filed 9/12/02.

Rejections Withdrawn

1. The rejection of claims 20 and 22 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendments to the claims. However, claims 1,3, 5, 7-9, 18, and 23 remain rejected as stated below.

2. The rejection of claims 1, 3, 5, 7-9, 18 -20, 22-23 under 35 U.S.C. 102(a) as being anticipated by Visvader et al., is withdrawn in view of the amendments to the claims and submitted priority document.

Response to Arguments

Rejection under 35 USC § 112 2nd paragraph

Claims 18 and 23 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for terms "derived from" and "derived parts" as stated below:

> Claims 18 and 23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
> Claims 18 and 23 are indefinite because the term "derived from" and "derived parts" in the claims are not clear. It is not clear that the terms "derived from" means "obtained from" and or "derived part" means "obtained parts". Therefore, the metes and bounds of the claims cannot be determined.

The response has been carefully considered but is deemed not to be persuasive. The response states that "derived from" and "derived parts" are commonly used in the art and "derived from" or "derived

part" has a different meaning than the term "obtained from" or obtained part". The Office agrees that the terms are commonly used terms in the art. However, the term used in the claim 18 and 23 reciting " *...variable domain of said deimmunized antibody is derived from the monoclonal antibody to LM04 and remaining immunoglobulin-derived parts of the demonized antibody molecule..."* does not clearly state how the domain of antibody is derived from or what the immunoglobulin derived part is. Thus, the metes and bounds of the claims cannot be determined. Thus, applicant's argument has not been found persuasive, and the rejection is maintained.

Rejection under 35 USC § 112 1st paragraph

1. Drawn to deposit of 16H2 and 20F8

Claims 18, 20, and 23 remain rejected under 35 U.S.C. 112, first paragraph, for lacks complete deposit information.

The response has been carefully considered but is deemed not to be persuasive. The response states that applicants have submitting a certification stating that the deposit has been made and verifying the viability of deposited materials. The response further states "all the restriction on availability of the hybridomas to the public will be irrevocably removed upon the granting the patent base upon the captioned application and said hybridomas will remain permanently available.....". in response to this statement, it is acknowledged that the office has received the copies of deposit receipts from European collection of cell cultures for both hybridomas 16H2 and 20F8, however, the requirement for biological deposit requires a statement or a affidavit/declaration for an assurance for the biological deposit as stated in the rejection below:

> If the deposit of hybridoma 16H2 or hybridoma 20F8 is not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of **an affidavit or declaration** by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:
>
> (a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request.
> (b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application.
> (c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest.
> (d) the deposits will be replaced if they should become nonviable or non-replicable.

Applicants have not provided such affidavit or declaration or any statement in the specification as an assurance for the biological deposit as stated above. Therefore, the rejection is maintained until such document is received by the Office.

2. *Drawn to enablement*- forming a complex of LMO/immunointeractive molecule or antibody mutant or variant thereof, derivative, analogue mutant thereof:

Claims 1, 3, 5, 7-9, 18, 22 and 23 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement as stated below:

> Claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.
>
> The factor considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re wands,* 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).
>
> The set of claims are broadly drawn to a method for detecting an aberrant cell or a predisposition to the development of mammary cells in a subject by screening the levels of complex of forming LMO4 or fragment, variant or derivative thereof with immunointeractive molecule, derivative, analogue or mutant thereof or with antibodies secreted hybridoma16H2 or hybridoma 20F8 or mutant or variant thereof.
> To satisfy the requirement of 112, 1st paragraph, it is necessary that the specification provide an enabling disclosure of how to make and use a claimed invention. The method objective of claims is a method for detecting an aberrant cell by formation of complex of LMO4 or its variants thereof with immunointeractive molecule, derivatives thereof or with antibodies secreted hybridoma16H2 or hybridoma 20F8 or its variant thereof. Thus, it would be expected that one of skill in the art would be able to detect an aberrant cell by determining the LMO4-antibody complex, or LMO4-immunointeractive molecule complex formation in a mammary cell without undue experimentation by using the claimed method.
> First, The specification on page 21, last paragraph, teaches that the "immunointeractive molecule" is any molecule having specificity and binding affinity for LM04 or its antigenic parts or its homologues or derivatives. Although the preferred immmunointeractive molecule is an immunglobulin molecule, the present invention extends to other immunointeractive molecules such as antibody fragments, single chain antibodies, deimmunized including humanized antibodies and T-cell associated antigen-binding molecules (TABMs). The specification also states that the subject immunointeractive molecule may be limited, bound or otherwise associated to any other proteinaceous or non-proteinaceous molecule or cell. However, the specification neither disclose functional or structural attributes of an immunointeractive molecule other than antibodies, nor any other immunointeractive molecule other than an antibody, which are immunoreactive to LMO4 and forming a complex with LMO4. The specification does not provide any method to detect LMO4 in a mammary cell or a working example, which enables immunointeractive molecule other than an antibody to detect LMO4 in a mammal cell. Therefore, one skilled in the art would not know how to use the claimed immunointeractive molecule other than an antibody based on the teachings in the prior art or instant specification.
>
> Secondly, The specification, on page 32, paragraphs 3, states that the invention extends to mutants, analogues, and derivative of the subject antibodies but which still retain specificity for LMO4. The specification further states on paragraph 4, that the terms "mutant" or "derivative" include one or more amino acid substitutions, additions and/or deletions. However, the specification does not teach any working example, which enables the composition in the claims that specifically bind to LMO4 protein or any LMO4

fragment, variant or derivative thereof. The specification does not teach any working example having identified a complex formed by LMO4 protein or a fragment, derivative or variant with an antibody secreted hybridoma16H2 or hybridoma 20F8 or mutant or variant thereof. The specification does not provide any teaching on antibody secreted by hybridoma 16H2 or 20F8, mutant, variant thereof which could form a complex with LMO4 protein or its variant. Thus, the instant specification fails to disclose the necessary parameters for using the method, which would lead to the detection of aberrant cell by screening the level of immunointerative molecule-LMO4 complex comprising fragment, mutant, variant, analogy thereof, or antibody-LMO4 complex comprising mutant, derivative, fragment variant thereof.
Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, the replacement of a single lysine at position 118 of the acidic fibroblast growth factor by a glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (Burgess et al, Journal of Cell biology, Vol 111, p2129-2138, 1990). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of the protein. Therefore, an undue experimentation is required to test any of claimed composition having a modulating function for any protein, which is even a minor different in its structure or sequence from a known protein.

Since the specification does not provide compositions used in the claims and not provide claimed method, since the specification does not provide any guidance for screening levels of the LMO4 complex using LMO4 or its variants, immunointeractive molecule, derivatives thereof or with antibodies secreted hybridoma16H2 or 20F8 or its variant thereof as discussed above, one skilled in the art would not know how to use the claimed method to detecting aberrant cells in a biological sample on the basis of teachings in the prior art or instant specification.

In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to detecting aberrant cells by the LMO4 complex formation with immunointeractive molecule, derivatives thereof or with antibodies secreted hybridoma16H2 or 20F8 or its variant thereof, one skilled in the art would be forced into under experimentation in order to practice the broadly claimed invention.

The response has been carefully considered but is deemed not to be persuasive. The response states that the specification teaches that a preferred immunointeractive molecule is an antibody, or antibody fragment or T-cell associated antigen-binding molecules (page 21-22) and also states that term "immunointeractive molecule" is clear to one skilled in the art in that the subject molecule is one which interacts with LM04 on an immunological basis.... In response to this argument, the specification, although teaches that immunointeractive molecule is an antibody or antibody fragment, but also teaches "*immunointeractive molecule is any molecule having specificity and binding affinity for LM04 or its antigenic parts or its homologues or derivatives*" (page 21, line 28-30) and "*subject immunointeractive molecule may be limited, bound, or otherwise associated to any other proteinaceous or non-proteinaceous molecule or cell*" (page 22, line 4-6). Thus, the "immunointeractive molecule" in the claims encompasses any compounds comprising any small molecule, any protein, or even nucleotide, which as long as binds to LM04 protein and form a complex with LM04. The specification neither discloses structural attributes of such immunointeractive molecules other than antibodies, nor any other immunointeractive molecule other than an antibody, which is immunoreactive to LMO4 and forms a

complex with LMO4. The specification does not provide any method to detect LMO4 in a mammary cell or a working example, which enables immunointeractive molecules other than an antibody to detect LMO4 in a mammal cell. Therefore, one skilled in the art would not know how to use the claimed immunointeractive molecule other than an antibody based on the teachings in the prior art or instant specification. Thus, applicant's argument has not been found persuasive, and the rejection is maintained.

In addition, the response states that in an effort to favorable advance prosecution, applicants have deleted the recitations of "derivatives", "mutants" and "variants" in the claims. The Office has withdrawn the rejection of claims 20 and 22 in view of the amendment to the claim by deleting the terms. However, the rejection of claim 23 is maintained since the claim still recites a method comprising using a hybridoma 16H2 or "mutant or variant thereof".

3. ***Drawn to enablement- at least one of the CDRs of the variable domain of deimmunized LMO4 antibody***

Claims 1, 3, 18 and 23 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement as stated below:

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."
>
> Claims are drawn to a method of for detecting an aberrant cell or a predisposition to the development of an aberrant cell in a subject by screening the levels of complex of forming LMO4 with an deimmunized antibody wherein at least one of the CDRs of the variable domain of the antibody derived from the monoclonal antibody to LMO4. Thus, the claims encompass using a monoclonal antibody, which does not contain a full set of 6 CDRs.
>
> The specification on para 20, PGpub 20050048528, states "invention contemplates a deimmunized antibody molecule having specificity for an epitope recognized by a monoclonal antibody to LMO4 wherein at least one of the CDRs of the variable domain of said deimmunized antibody is derived from the said monoclonal antibody to LMO4 and the remaining immunoglobulin-derived parts of the deimmunized antibody molecule are derived from an immunoglobulin or an analogue thereof from the host for which the antibody is to be deimmunized". However, the specification does not provide any working example or any evidence to enable claimed antibody having at least one of the CDRs specifically binding to LMO4 antigen.
>
> It is well established in the art that the formation of an intact antigen-binding site of all antibodies requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs or hypervariable regions, which provide the majority of the contact residues for the binding of the antibody to its target epitope (Paul, Fundamental Immunology, 3rd Edition, 1993, pp. 292-295, under the heading "Fv Structure and Diversity in Three Dimensions"). The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity, which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and

that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites (Paul, page 293, first column, lines 3-8 and line 31 to column 2, line 9 and lines 27-30). Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al., (Proc. Natl. Acad. Sci. USA 1982 Vol. 79: page 1979). Rudikoff et al., teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function. It is unlikely that deimmunized antibody, thereof as defined by the claims, which may contain less than the full complement of CDRs from the heavy and light chain variable regions have the required binding function. Applicants have provided insufficient evidence or nexus that would lead the skilled artisan to predict the ability of using a deimmunized antibody, containing fewer than 6 CDRs, resulting in the antibody that retains the antigen specificity of the parental non-human antibody. One of skill in the art would neither expect nor predict the appropriate functioning of the antibody as broadly as is claimed.

Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention as it pertains to a method of using a deimmunized antibody containing at least one of the CDRs. Undue experimentation would be required to use the invention commensurate with the scope of the claims from the written disclosure.

The response has been carefully considered but is deemed not to be persuasive. The response states (page 18) that the functional limitation would inherently require that sufficient CDRs are derived from the anti-LM04 antibody to confer epitopic specificity, as such, the present application provides sufficient description and guidance for one skilled in the art to practice the claimed method of using deimmunized antibody containing at least one CDR derive from the anti-LM04 monoclonal antibody. In response to this argument, the claims are drawn to a method of detecting an aberrant cells comprising screening or determining the levels of a LM04-antibody complex. The Office does agree the functional limitation of forming an antibody-LM04 complex would require sufficient CDRs from the antibody to LM04. However, the claims 18 and 23 limit the antibody to at least one of the CDRs of the variable domain of the deimmunized antibody of LM04. Again, as discussed in the rejection:

The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity, which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites (Paul, page 293, first column, lines 3-8 and line 31 to column 2, line 9 and lines 27-30). Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function.

The specification does not provide any evidence for one skilled in the art to enable claimed method using a deimmunized antibody at least one of the CDRs or having a small change in their CDRs to bind to LMO4 and form a complex. Thus, undue experimentation would be required to practice

claimed invention using an antibody to LM04 with at least one of the CDRs. Thus, applicant's argument has not been found persuasive, and the rejection is maintained.

The following is a New Ground of rejection-based on newly added, amendment to the claims and new consideration

Rejection under 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5, 7-9, 18-20, 22, 23 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Paml et al., (US patent application publication, 2003/0092009, effective file date Nov 16, 2000).

Paml et al., disclose a method of detecting LMO4 with auto-antibody to LMO4 from serum of cancer patients. Paml et al., disclose antibody to LMO4 and fragment of LMO4 form a complex (table 4) and the disease comprising abnormal growth neoplastic cells can characterized by the presence antibody to LMO4 (form a complex with LMO4 polypeptide) in patient's blood (page 18, example 2).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER